

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Dr. Bashir Kh

Patient file# : 114457

Date 21/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 43.6 K2 44 K1 Axis 173
 3. Intra-op full corneal thickness (microns) 531 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.5
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : _____
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J487
 5. Blade Lot # or Single-Use Lot # : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec

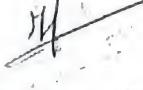
Yes No

Yes No

2. Potential intra-operative events

• Pseudo Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, what was the flap thickness in microns? <u>531</u>
• Unacceptable thickness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	❖ Pre-op full corneal thickness <u>531</u>
• Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	❖ Residual stromal bed thickness <u>463</u>
• Partial flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	❖ Calculated Flap thickness <u>68</u>
• Free cap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Decentred Flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Stromal Incision	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Epithelium patch	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Dr. Bashir Kh Patient file# : 14457 Date 21/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 43.8 K2 44 K1 Axis 26.4
 3. Intra-op full corneal thickness (microns) 532 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.4
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : _____
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487
 5. Blade Lot # or Single-Use Lot # : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No
- Unacceptable thickness Yes No
- Button-hole Yes No
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

If yes, what was the flap thickness in microns?

Pre-op full corneal thickness

532

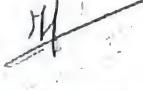
Residual stromal bed thickness

452

Calculated Flap thickness

70

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Dr. Baskinik Date 14/6/2015 Patient file# : 14468

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.6 K2 44.3 K1 Axis 63
 3. Intra-op full corneal thickness (microns) 562 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.9
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : _____
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : 51487
 5. Blade Lot # or Single-Use Lot # : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

No

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

• Pseudo Button-hole	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, what was the flap thickness in microns?
• Unacceptable thickness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Pre-op full corneal thickness <u>562</u>
• Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Residual stromal bed thickness <u>496</u>
• Partial flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Calculated Flap thickness <u>76</u>
• Free cap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Decentred Flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Stromal Incursion	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Epithelium patch	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Dr. Basleith Patient file# : 144 68 Date 14/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 47.6 K2 44.8 K1 Axis 175
 3. Intra-op full corneal thickness (microns) 558 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.6
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : _____
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J 1487
 5. Blade Lot # or Single-Use Lot # : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? If yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 558
- Unacceptable thickness Yes No Residual stromal bed thickness 490
- Button-hole Yes No Calculated Flap thickness 68
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Basherikh Patient file# : 14361 Date 14/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 43 K2 45.2 K1 Axis 3.3
 3. Intra-op full corneal thickness (microns) 527 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.8
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : _____
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-K™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487
 5. Blade Lot # or Single-Use Lot # : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 8143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

W

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No
- Unacceptable thickness Yes No
- Button-hole Yes No
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

If yes, what was the flap thickness in microns?

Pre-op full corneal thickness 527

Residual stromal bed thickness 443

Calculated Flap thickness 84

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

 <i>Date d'application : 06/07/2011</i>	Flap complication report	EAQA018 / C	<i>Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48</i> 

Surgeon: Dr. Basker VL Patient file#: 14361 Date 14/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 43 K2 44.4 K1 Axis 172.5
 3. Intra-op full corneal thickness (microns) 533 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.8
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number: 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-K™
 Evo2 Speed adaptator s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number: J1487
 5. Blade Lot # or Single-Use Lot #: 1114112
 6. Moria sterile tubing Reference 19138 Batch number: 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No Yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? 533
 Pre-op full corneal thickness 463
- Unacceptable thickness Yes No Residual stromal bed thickness 70
- Button-hole Yes No Calculated Flap thickness 533
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incursion Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

 <i>Date d'application : 06/07/2011</i>	Flap complication report	EAQA018 / C	<i>Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48</i> 

Surgeon: D. Basheikh Patient file#: 14628 Date: 21/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 41.5 K2 41.9 K1 Axis 115
 3. Intra-op full corneal thickness (microns) 548 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.00
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptator s/n _____ Speed selection 21 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : 21487
 5. Blade Lot # or Single-Use Lot # : 1114112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

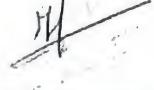
1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No If yes, suction time? _____ sec
 Yes No
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 548
- Unacceptable thickness Yes No Residual stromal bed thickness 477
- Button-hole Yes No Calculated Flap thickness 71
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon:

Patient file# :

Date

REPORT OF INTRAOPERATIVE FLAP COMPLICATION**A) PATIENT**

1. Eye OD OS
 2. Keratometries K1 42.2 K2 42.3 K1 Axis 5
 3. Intra-op full corneal thickness (microns) 563 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.00
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487
 5. Blade Lot # or Single-Use Lot # : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

no

If yes, suction time? _____ sec

 Yes No Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No
- Unacceptable thickness Yes No
- Button-hole Yes No
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

If yes, what was the flap thickness in microns?

563

❖ Pre-op full corneal thickness

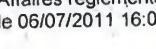
481

❖ Residual stromal bed thickness

82

❖ Calculated Flap thickness

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

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	<i>Date d'application : 06/07/2011</i>		

Surgeon: AHMED HUSEIN Patient file# : 11568 Date 17/06/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye	<input checked="" type="checkbox"/> OD	<input type="checkbox"/> OS
2. Keratometries	K1 <u>42.0</u>	K2 <u>43.2</u> K1 Axis <u>23-1</u>
3. Intra-op full corneal thickness (microns)	<u>507</u>	<input checked="" type="checkbox"/> Ultrasound <input type="checkbox"/> Imaging <input type="checkbox"/> Scheimpflug camera
4. White-to-White (mm)	<u>12.1 mm</u>	<u>11mm</u> <u>10mm</u> <u>9mm</u>
5. Ametropic correction?	<input checked="" type="checkbox"/> Myopic	<input type="checkbox"/> Hyperopic <input checked="" type="checkbox"/> Astigmatic
6. Additional comments on the patient's eye	<hr/>	

B) MATERIAL

MATERIALS
 1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SBK
 5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT: 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3148C02
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec

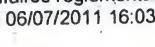
Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
- Unacceptable thickness Yes No Pre-op full corneal thickness 507
- Button-hole Yes No Residual stromal bed thickness 437
- Partial flap Yes No Calculated Flap thickness 70
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48
			

Surgeon: AHMED HUSTON Patient file# : 14568 Date 13/06/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
2. Keratometries K1 41.8 K2 43.4 K1 Axis 162°
3. Intra-op full corneal thickness (microns) 528 Ultrasound Imaging Scheimpflug camera
4. White-to-White (mm) 12.1 mm DENT 10 mm
5. Ametropic correction? Myopic Hyperopic Astigmatic
6. Additional comments on the patient's eye _____

B) MATERIAL

MATERIALS: Evo2 Evo3 Evo3E Other Serial Number : 8113
 1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptator s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SBK
 5. Blade Lot # or Single-Use Lot # : S1161E USE LOT: 1144 12
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 9. 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? 528
- Unacceptable thickness Yes No Pre-op full corneal thickness 448
- Button-hole Yes No Residual stromal bed thickness 80
- Partial flap Yes No Calculated Flap thickness
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par: Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmed Hussein

Patient file# : 14501

Date 15/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 44.2 K2 45 K1 Axis 3.2
 3. Intra-op full corneal thickness (microns) 595 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.2 Pentacam HR
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SBK
 5. Blade Lot # or Single-Use Lot # : Single use LOT: 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? 1 eye
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No If yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? 595
- Unacceptable thickness Yes No Pre-op full corneal thickness 595
- Button-hole Yes No Residual stromal bed thickness 514
- Partial flap Yes No Calculated Flap thickness 81
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmed Hussein Patient file# : 14561 Date 15/6/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 43.7 K2 45.7 K1 Axis 171.3
 3. Intra-op full corneal thickness (microns) 598 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.3
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J 1487
 5. Blade Lot # or Single-Use Lot # : Single use 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? 2
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

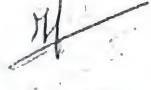
1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No If yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 596
- Unacceptable thickness Yes No
- Button-hole Yes No Residual stromal bed thickness 522
- Partial flap Yes No Calculated Flap thickness 74
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incursion Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

 Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: AHMED HASSAIN Patient file# : 14540 Date 10/06/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.9 K2 43.4 K1 Axis 26.9
 3. Intra-op full corneal thickness (microns) 627 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.5 Plano Hyperopic Astigmatic
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptator s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : 51487 SPK
 5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec

Yes No
 Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No
- Unacceptable thickness Yes No
- Button-hole Yes No
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

If yes, what was the flap thickness in microns?

Pre-op full corneal thickness 627
 Residual stromal bed thickness 530
 Calculated Flap thickness 88

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Christophe Hirsch Patient file# : 14570 Date 10/06/2011

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 43.0 K2 43.3 K1 Axis 206
 3. Intra-op full corneal thickness (microns) 620 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.4 mm Pentacam 11.6
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 813
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: J1487 SBIC
 4. Handpiece serial number : J1487 SBIC
 5. Blade Lot # or Single-Use Lot # : SINGLE USE 101 : 1144 112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

No

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? 620
 Pre-op full corneal thickness 620
- Unacceptable thickness Yes No Residual stromal bed thickness 551
- Button-hole Yes No Calculated Flap thickness 69
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: CILMEO HUSSEIN Patient file# : 14508 Date 10/06/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.1 K2 42.6 K1 Axis 8.1
 3. Intra-op full corneal thickness (microns) 533 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.3 Pentacam HR
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 813
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SPK
 5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT : 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No Yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 533
- Unacceptable thickness Yes No Residual stromal bed thickness 468
- Button-hole Yes No Calculated Flap thickness 65
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

 <i>Date d'application : 06/07/2011</i>	Flap complication report	EAQA018 / C	<i>Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48</i> 

Surgeon: AHMED HUSSEIN Patient file# : 14508 Date 10/06/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.4 K2 42.5 K1 Axis 157.4
 3. Intra-op full corneal thickness (microns) 558 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.1 PENTOCAM H2
 5 Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1427 SBK
 5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT# 114411
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? If yes, suction time? _____ sec
 Yes No
- Was the suction good and stable during the pass?
 Yes No
- Was the forward movement smooth and regular?
 Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 558
- Unacceptable thickness Yes No
 Residual stromal bed thickness 474
- Button-hole Yes No
 Calculated Flap thickness 84
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussein Patient file#: 14577 Date

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.6 K2 43.2 K1 Axis 162.5
 3. Intra-op full corneal thickness (microns) 560 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.6 mm Rentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8117
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SBIC
 5. Blade Lot # or Single-Use Lot # : Single use lot 144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? Yes No
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No
- Unacceptable thickness Yes No
- Button-hole Yes No
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

If yes, what was the flap thickness in microns? _____

Pre-op full corneal thickness 560

Residual stromal bed thickness 493

Calculated Flap thickness 473

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par: Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: CH intro thesein Patient file# : 14516 Date 10/06/2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.0 K2 42.4 K1 Axis 23.0
 3. Intra-op full corneal thickness (microns) 57.3 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.9 16.1 16.1 Myopic Hyperopic Astigmatic
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 813
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-K™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1427 50K
 5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT: 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

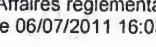
1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No If yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

• Pseudo Button-hole	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, what was the flap thickness in microns? _____
• Unacceptable thickness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	• Pre-op full corneal thickness <u>57.3</u>
• Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	• Residual stromal bed thickness <u>49.9</u>
• Partial flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	• Calculated Flap thickness <u>74</u>
• Free cap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Decentred Flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Stromal Incision	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Epithelium patch	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	<i>Date d'application : 06/07/2011</i>		

Surgeon: AHMED HUSSEIN **Patient file# :** 1 **Date**

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS

2. Keratrometries K1 _____ K2 _____ K1 Axis _____

3. Intra-op full corneal thickness (microns) _____ Ultrasound Imaging Scheimpflug camera

4. White-to-White (mm) _____ PENTACONIC HR

5 Ametropic correction? Myopic Hyperopic Astigmatic

6. Additional comments on the patient's eye

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113

2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptator s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)

3. Microkeratome metal head 150 130 110 90 Serial Number: _____

4. Handpiece serial number : J1487 SBK

5. Blade Lot # or Single-Use Lot # : SINGLE USE LOT: 1144112

6. Moria sterile tubing Reference 19138 Batch number : 3143602

7. On approximately how many eyes this specific set had been used before this complication? _____

8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC

10 Stop 7 7.5 8 8.5 8.75 9 Other _____

11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

Handwritten note: ✓

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No
- Unacceptable thickness Yes No
- Button-hole Yes No
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

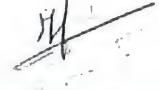
If yes, what was the flap thickness in microns? _____

❖ Pre-op full corneal thickness 580

❖ Residual stromal bed thickness 497

❖ Calculated Flap thickness 74

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussein Patient file# : 14603 Date 16 JUNE 2013

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 41.0 K2 47.8 K1 Axis 176.6
 3. Intra-op full corneal thickness (microns) 562 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.0mm Pentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 813
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : 51487 SBK
 5. Blade Lot # or Single-Use Lot # : Single Use Lot 144112
 6. Moria sterile tubing Reference 19138 Batch number : 3143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?



If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No
- Unacceptable thickness Yes No
- Button-hole Yes No
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

If yes, what was the flap thickness in microns?

Pre-op full corneal thickness

562

Residual stromal bed thickness

478

Calculated Flap thickness

84

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQAO18 / C	Approuvé(e) par: Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussein Patient file#: 14560 Date 17 June 2011

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
2. Keratometries K1 41.0 K2 42.9 K1 Axis 71.3
3. Intra-op full corneal thickness (microns) 546 Ultrasound Imaging Scheimpflug camera
4. White-to-White (mm) 11.9 mm Pentacam
5. Ametropic correction? Myopic Hyperopic Astigmatic
6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
3. Microkeratome metal head 150 130 110 90 Serial Number: _____
4. Handpiece serial number : 51487 SPK
5. Blade Lot # or Single-Use Lot # : Single use LOT 14412
6. Moria sterile tubing Reference 19138 Batch number : 314 3602
7. On approximately how many eyes this specific set had been used before this complication? _____
8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
- 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? If yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
- Unacceptable thickness Yes No Pre-op full corneal thickness 546
- Button-hole Yes No Residual stromal bed thickness 476
- Partial flap Yes No Calculated Flap thickness 70
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par: Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Husein Patient file#: 14560 Date 17 June 2011

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 41.40 K2 42.6 K1 Axis 156.9
 3. Intra-op full corneal thickness (microns) 563 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.1mm Pentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8117
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : 1487 SBK
 5. Blade Lot # or Single-Use Lot # : Single Use LOT 144112
 6. Moria sterile tubing Reference 19138 Batch number : 314 3402
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec
 Yes No
 Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 563
- Unacceptable thickness Yes No Residual stromal bed thickness 480
- Button-hole Yes No Calculated Flap thickness 83
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Dr. Ahmad Hussein Patient file# : 14578 Date 18 JUNE 2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 40.7 K2 41.0 K1 Axis 0-1
 3. Intra-op full corneal thickness (microns) 588 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.6mm Pentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-K™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SBK
 5. Blade Lot # or Single-Use Lot # : Single use LOT 144112
 6. Moria sterile tubing Reference 19138 Batch number : 314 3602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0' +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No If yes, suction time? _____ sec
 Yes No
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 588
- Unacceptable thickness Yes No Residual stromal bed thickness 500
- Button-hole Yes No Calculated Flap thickness 588
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQAO18 / C	Approuvé(e) par: Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussein Patient file#: 14578 Date 18 June 2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 41.0 K2 41.2 K1 Axis 32.7
 3. Intra-op full corneal thickness (microns) 596 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 11.8 mm Pentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number: 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-K™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number: J1467 SBK
 5. Blade Lot # or Single-Use Lot #: Single use LOT 144112
 6. Moria sterile tubing Reference 19138 Batch number: 314 3602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? No
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

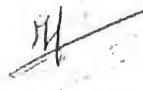
If yes, suction time? _____ sec

Yes No
 Yes No

2. Potential intra-operative events

• Pseudo Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, what was the flap thickness in microns?
• Unacceptable thickness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	❖ Pre-op full corneal thickness <u>596</u>
• Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	❖ Residual stromal bed thickness <u>514</u>
• Partial flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	❖ Calculated Flap thickness <u>82</u>
• Free cap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Decentred Flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Stromal Incision	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Epithelium patch	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussein Patient file#: 14601 Date 16 JUNE 2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.2 K2 42.4 K1 Axis 15.0
 3. Intra-op full corneal thickness (microns) 547 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.4mm Rentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SBK
 5. Blade Lot # or Single-Use Lot # : Single use LOT 14412
 6. Moria sterile tubing Reference 19138 Batch number : 314 3602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

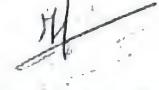
C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:
 • Was suction time longer or shorter than usual? ND If yes, suction time? _____ sec
 • Was the suction good and stable during the pass? Yes No
 • Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

• Pseudo Button-hole Yes No If yes, what was the flap thickness in microns?
 • Unacceptable thickness Yes No Pre-op full corneal thickness 547
 • Button-hole Yes No Residual stromal bed thickness 4166
 • Partial flap Yes No Calculated Flap thickness 81
 • Free cap Yes No
 • Decentred Flap Yes No
 • Stromal Incision Yes No
 • Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussain Patient file#: 14601 Date 16 JUNE 2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 42.4 K2 42.9 K1 Axis 136.4
 3. Intra-op full corneal thickness (microns) 554 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.3 mm Pentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : J1487 SBK
 5. Blade Lot # or Single-Use Lot # : Single use lot 144112
 6. Moria sterile tubing Reference 19138 Batch number : J143602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H -1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? NO
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec

Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? 554
- Unacceptable thickness Yes No Pre-op full corneal thickness 475
- Button-hole Yes No Residual stromal bed thickness 79
- Partial flap Yes No Calculated Flap thickness
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

Moria	Flap complication report	EAQA018 / C	Approuvé(e) par: Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussain

Patient file#: 14610

Date

17 JUNE 2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 41.2 K2 41.4 K1 Axis 17.7
 3. Intra-op full corneal thickness (microns) 581 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.4 mm Rentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8117
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : 51487 SBK
 5. Blade Lot # or Single-Use Lot # : Single use lot 144112
 6. Moria sterile tubing Reference 19138 Batch number : 314 3602
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H 1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? NO
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

If yes, suction time? _____ sec

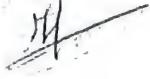
Yes No

Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 581
- Unacceptable thickness Yes No Residual stromal bed thickness 495
- Button-hole Yes No Calculated Flap thickness 86
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

 <i>Date d'application : 06/07/2011</i>	Flap complication report	EAQA018 / C	<i>Approuvé(e) par : Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48</i> 

Surgeon: Ahmad Hussein

Patient file#: 14610

Date 17 JUNE 2015

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye OD OS
 2. Keratometries K1 40.9 K2 41.3 K1 Axis 71.4
 3. Intra-op full corneal thickness (microns) 58.6 Ultrasound Imaging Scheimpflug camera
 4. White-to-White (mm) 12.4 mm Pentacam
 5. Ametropic correction? Myopic Hyperopic Astigmatic
 6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
 2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
 3. Microkeratome metal head 150 130 110 90 Serial Number: _____
 4. Handpiece serial number : 51487 SBK
 5. Blade Lot # or Single-Use Lot # : Single Use Lot. 1144112
 6. Moria sterile tubing Reference 19138 Batch number : 2143002
 7. On approximately how many eyes this specific set had been used before this complication? _____
 8. Ring Disposable Single use H 1 0 +1 +2 +3 -1 LC
 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
 11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual? NO If yes, suction time? _____ sec
- Was the suction good and stable during the pass? Yes No
- Was the forward movement smooth and regular? Yes No

2. Potential intra-operative events

- Pseudo Button-hole Yes No If yes, what was the flap thickness in microns? _____
 Pre-op full corneal thickness 58.6
- Unacceptable thickness Yes No Residual stromal bed thickness 51.4
- Button-hole Yes No Calculated Flap thickness 72
- Partial flap Yes No
- Free cap Yes No
- Decentred Flap Yes No
- Stromal Incision Yes No
- Epithelium patch Yes No

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

	Flap complication report	EAQA018 / C	Approuvé(e) par: Jean Paul MERCEREAU Directeur Assurance Qualité et Affaires réglementaires le 06/07/2011 16:03:48 
	Date d'application : 06/07/2011		

Surgeon: Ahmad Hussein Patient file#: 14519 Date 14 JUNE 2011

REPORT OF INTRAOPERATIVE FLAP COMPLICATION

A) PATIENT

1. Eye 90° OS
2. Keratometries K1 39.6 K2 41.2 K1 Axis 179.6
3. Intra-op full corneal thickness (microns) 564 Ultrasound Imaging Scheimpflug camera
4. White-to-White (mm) 12.3 mm calliper
5. Ametropic correction? Myopic Hyperopic Astigmatic
6. Additional comments on the patient's eye _____

B) MATERIAL

1. Console Evo2 Evo3 Evo3E Other Serial Number : 8113
2. Microkeratome ONE ONE Use CB CBSU M2 M2SU ONE Use-Plus EPI-k™
 Evo2 Speed adaptor s/n _____ Speed selection 1 or 2 (For M2/M2SU and One Use Plus only)
3. Microkeratome metal head 150 130 110 90 Serial Number: _____
4. Handpiece serial number : J1487 SBK
5. Blade Lot # or Single-Use Lot # : Single use lot 144112
6. Moria sterile tubing Reference 19138 Batch number : 3143602
7. On approximately how many eyes this specific set had been used before this complication? _____
8. Ring Disposable Single use H 0 +1 +2 +3 -1 LC
- 10 Stop 7 7.5 8 8.5 8.75 9 Other _____
11. New blade? Yes No (Check "No" for the second eye in bilateral simultaneous LASIK)

C) INTRA-OPERATIVE RESULTS

1. Characteristics of suction and automated translation:

- Was suction time longer or shorter than usual?
- Was the suction good and stable during the pass?
- Was the forward movement smooth and regular?

NO

If yes, suction time? _____ sec
 Yes No
 Yes No

2. Potential intra-operative events

• Pseudo Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, what was the flap thickness in microns? _____
• Unacceptable thickness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	❖ Pre-op full corneal thickness <u>564</u>
• Button-hole	<input type="checkbox"/> Yes <input type="checkbox"/> No	❖ Residual stromal bed thickness <u>49.6</u>
• Partial flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	❖ Calculated Flap thickness <u>6.8</u>
• Free cap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Decentred Flap	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Stromal Incision	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Epithelium patch	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Draw the location of the partial flap or of the pseudo or "see-through" button-hole

